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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,934	06/03/2002	Gour Mukherji	RLL-165US	3005
26815	7590	08/23/2005	EXAMINER	
RANBAXY INC. 600 COLLEGE ROAD EAST SUITE 2100 PRINCETON, NJ 08540			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/936,934

Applicant(s)

MUKHERJI ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

**Acknowledgment of Papers Received:** Amendment/Response dated 4/29/05.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,4,7,8,11-14,16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Mehta (USPN 4,800,087 hereafter '087). The claims are drawn to composition comprising a film coating where the coating comprises film-forming materials in combination with high viscosity swellable polymers.

3. The '087 patent disclose a formulation comprising a coated core where the coating comprises film-forming polymers and swellable polymers (abstract). The coating includes methacrylic acid copolymers, polymethacrylate-methylmethacrylate copolymers, and polyvinyl alcohol (col. 24-63). The formulation further comprises lactose, starch; plasticizers such as propylene glycol, triacetin, diethyl phthalate, and polyethylene glycol (col. 7, lin. 59-68; col. 9, lin. 5-34). The formulation of coated particles is formulated into sprinkles, powders, chewable tablets and other well-known oral forms (examples). These disclosures render the claims anticipated.

4. Claims 1,4,6-8,11-14,16 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Dunn (USPN 5,681,581 hereafter '581). The claims are drawn to composition comprising a

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film coating where the coating comprises film-forming materials in combination with high viscosity swellable polymers.

5. The '581 patent discloses coated particles where the coating comprises multiple polymers including methacrylic acid copolymers, hydrogel polymers such as Carbopol, and cellulosic polymers (col. 6, lin. 47-col. 7, lin. 50). The formulation further comprises plasticizers such as diethyl phthalate and polyethylene glycol (col. 8, lin. 14-33); diluents such as lactose (col. 7, lin. 57-67) and lubricants such as magnesium stearate (col. 8, lin. 1-12). The coated particles are formed into tablets for oral delivery (examples). These disclosures render the claims anticipated.

### *Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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8. Claims 3,5,9,10,15 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Mehta (USPN 4,800,087 hereafter '087). The claims are drawn to coated particles with specific concentrations of components coated on them.

9. As discussed above the formulation discloses coated particles where the coating comprises multiple polymers, and the formulation further comprises other common excipients including lubricants, diluents, and plasticizers. The reference discloses these component in various concentrations, some of which within the limitation of the instantly claimed invention. However it is the position of the Examiner that these concentrations do not impart patentability on the claims of the instant invention. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

10. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

11. With these things in mind it would have been obvious to one of ordinary skill to follow the teachings of the '087 reference in order to provide an optimized coated particle with improve release. It would have been obvious to one of ordinary skill in the art to follow these teachings

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with an expected result of a controlled release formulation capable of intestinal release of an active agent.

***Response to Arguments***

12. Applicant's arguments with respect to claims 1,3-18 have been considered but are moot in view of the new ground(s) of rejection.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young  
Examiner  
Art Unit 1618

  
MP Young

  
THURMAN K. PAGE  
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